

ATTORNEY'S DOCKET NUMBER
CS-8558/BCS033001

U.S. APPLICATION NO. (If known, see 47 CFR 1.5)

PRIORITY DATE CLAIMED
17 January 2003 (17.01.2003)

INTERNATIONAL APPLICATION NO.
PCT/EP2004/000058

INTERNATIONAL FILING DATE
08 January 2004 (8.01.2004)

TITLE OF INVENTION 9-KETOSPINOSYN DERIVATIVES

APPLICANT(S) FOR DO/EO/US MALSAM, Olga; LOSEL, Peter; BECK, Michael E.; EBBINGHAUS-KINTSCHER, Ulrich; VELTEN, Robert; JESCHKE, Peter; MOHRLE, Volker; FRODE, Rita and EBERZ, Gunther
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US)

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☒ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☒ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information: Preliminary Amendment w/Abstract Page; PTO Form 1449 and copies of foreign patents and articles listed therein

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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|---|--------------|---|---------|---|----------|
| U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/541442 | | INTERNATIONAL APPLICATION NO. PCT/EP2004/000058 | | ATTORNEY'S DOCKET NUMBER CS-8558/BCS033001 | |
| The following fees have been submitted | | | | CALCULATIONS PTO USE ONLY | |
| 21. <input checked="" type="checkbox"/> Basic national fee..... \$300 | | | | \$ | 300.00 |
| 22. <input checked="" type="checkbox"/> Examination fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)..... \$100 All other situations..... \$200 | | | | \$ | 200.00 |
| 23. <input checked="" type="checkbox"/> Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... \$100 International Search Report prepared and provided to the Office..... \$400 All other situations..... \$500 | | | | \$ | 500.00 |
| TOTAL OF 21, 22 and 23 = | | | | \$ | 1,000.00 |
| <input checked="" type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | | | | |
| Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE | | |
| 139 - 100 = | 39 /50 = | 2 | x \$250 | \$ | 500.00 |
| Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(h)). | | | | \$ | 0.00 |
| CLAIMS | NUMBER FILED | NUMBER EXTRA | RATE | | |
| Total claims | 14 - 20 = | 0 | x \$ 50 | \$ | 0.00 |
| Independent claims | 3 - 3 = | 0 | x \$200 | \$ | 0.00 |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable) | | | | \$ | 0.00 |
| TOTAL OF ABOVE CALCULATIONS = | | | | \$ | 1,500.00 |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2. | | | | \$ | 0.00 |
| SUBTOTAL = | | | | \$ | 1,500.00 |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). | | | | \$ | 0.00 |
| TOTAL NATIONAL FEE = | | | | \$ | 1,500.00 |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property | | | | \$ | 40.00 |
| TOTAL FEES ENCLOSED = | | | | \$ | 1,540.00 |
| | | | | Amount to be refunded: | \$ |
| | | | | Amount to be charged: | \$ |

- a. ☐ A check in the amount of \$ _____ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 50-2510 in the amount of \$ 1,540.00 to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-2510. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:
34469

Richard E.L. Henderson
SIGNATURE

Richard E.L. Henderson
NAME

31,619
REGISTRATION NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES RECEIVING OFFICE

10754142

| | | | |
|--|---------------------|---|-------------------|
| Express Mail mailing number: | ED 780112807 US | Date of deposit: | 6 July 2005 |
| File reference no.: | CS-8558/BCS 03-3001 | International application no. (if known): | PCT/EP2004/000058 |
| Title of the invention: 9-KETOSPINOSYN DERIVATIVES | | | |
| Earliest priority date claimed (Day/Month/Year): | | 17 Jan 2003 (17.01.2003) | |

☒ This is a new International Application

SCREENING DISCLOSURE INFORMATION:

In order to assist in screening the accompanying international application for purposes of determining whether a license for foreign transmittal should and could be granted and for other purposes, the following information is supplied. (check as many boxes as apply):

☒ The invention disclosed was not made in the United States of America.

☒ There is no prior U.S. application relating to this invention.

☐ The following prior U.S. application(s) contain subject matter which is related to the invention disclosed in the attached international application. (NOTE: priority to these applications may or may not be claimed on the Request form PCT/RO/101) and this listing does not constitute a claim for priority.)

| | | | |
|-----------------|--|----------|--|
| application no. | | filed on | |
| application no. | | filed on | |

☐ The present international application contains additional subject matter not found in the prior U.S. application(s) identified above. The additional subject matter is found on pages _____ and ☐ DOES NOT ALTER ☐ MIGHT BE CONSIDERED TO ALTER the general nature of the invention in a manner which would require the U.S. application to have been made available for inspection by the appropriate defense agencies under 35 U.S.C. 181 and 37 C.F.R. 5.15.

Itemized list of contents

| | | | |
|---|-----|--|----|
| Sheets of Request form: | 2 | Check no.: | -- |
| Sheets of description (excluding sequence listing): | 125 | Return receipt postcard: | 1 |
| Sheets of claims: | 13 | Power of attorney: | -- |
| Sheets of abstract: | 1 | Certified copy of priority document (specify): | -- |
| Sheets of drawings: | -- | Other (specify): Preliminary Amendment w/Abstract Page; PTO Form 1449 and copies of foreign patents and articles | |
| Sheets of sequence listing: | -- | | |
| Sequence listing diskette/CD: | -- | | |
| Tables related to sequence listing CD: | -- | | |

The person signing this form is:

| | |
|---|------------------------|
| <input type="checkbox"/> Applicant | Richard E.L. Henderson |
| <input checked="" type="checkbox"/> Attorney/Agent (Reg. No.) 31,619 | |
| <input type="checkbox"/> Common Representative | |
| Name of person signing | |
| Signature <i>Richard E.L. Henderson</i> | |

This collection of information is required by 37 CFR 1.10 and 1.412. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.